

## Environmental Assessment

1. **Date:** October 7, 1993
2. **Name of applicant/petitioner:**  
Analytical Systems Engineering Corporation (ASEC)
3. **Address:**  
5400 Shawnee Road, Suite 100  
Alexandria, VA 22312
4. **Description of proposed action:**

It is proposed to amend 21 CFR 179 to permit the use of linear accelerators as a sources of radiation of energies up to 10 MeV and doses of up to 0.5 Gy for radiographic inspection of large cargo containers and vehicles. The U.S. Customs Service, Federal Aviation Administration, Department of Defense, and Department of Transportation have expressed strong interest in this system for the detection of contraband such as illegal drugs, explosives, weapons, hazardous materials, and other unauthorized goods.

An unknown percentage of the cargo to be examined may contain foods which therefore may incidentally be subjected to the radiation exposure. Without approval for the use of the inspection system with foods, cargo containers and vehicles would have to be manually searched and foods removed prior to inspection thereby significantly impairing the efficiency and effectiveness of the inspection process.

The principle of operation is similar to that of equipment used for inspection of carry-on luggage in airports. However, this system is designed to handle intermodal containers (approximately 8' h x 48' l x 8' w).

The object to be examined is moved through thin fan shaped beams of radiation produced by one horizontal and one vertical oriented radiation source. Each beam is approximately 5 mm in width, and the beams are separated by a distance of approximately 5 ft. The transmitted radiation is detected by CsI(Tl) scintillation detectors. The signals from each detector are integrated, amplified and transmitted to a computer where it is converted into a visible image. The computer also provides image analysis and enhancement capabilities. The use of two sources of radiation and detectors provides images in both the horizontal and vertical planes. Feasibility studies have established that the most appropriate radiation source for this application is 10 MeV x-rays produced by linear accelerators.

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Linear accelerators are manufactured at several locations in the world. Within the United States, linear accelerators are manufactured primarily in the State of California. They

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are also manufactured in Japan, France, Germany, Russia, the United Kingdom, and the Peoples Republic of China.

It is anticipated that inspection facilities will primarily be associated with ports of entry and transportation centers with large volumes of containerized cargo, such as airports and seaports. Special dedicated facilities for the inspection system would be constructed in areas with restricted entry and not generally accessible to the general public.

A test facility funded by the Department of Defense, Advanced Research Projects Agency (ARPA) through a contract with Analytical Systems Engineering Corporation (ASEC) has been constructed at the port in Tacoma, Washington to develop, demonstrate, and characterize the effectiveness of various non-invasive inspection technologies for detecting illegal drugs and other contraband transported by truck, railroad, and intermodal carriers.

The testbed site covers an area of approximately 6 acres and has four main buildings. In summary, the inspection takes place within a totally enclosed radiation shielded building 272 feet long and 60 feet high. Radiation shielding of the building is provided by the concrete and lead construction materials and supplemented with earthen berms constructed adjacent to the inspection building.

Radiation shielding is sufficient to insure that personnel radiation exposures are within the limits established by the State of Washington, other regulatory agencies, and the recommendations of other standards setting organizations such as the National Council on Radiation Protection. The maximum radiation levels at the perimeter fence was measured to be 0.320 mrem/hr. Considering the operational plan of 4 hours of beam on time per week, the maximum radiation level would be 1.28 mrem/week. Recommended and regulatory requirements for non-occupational exposure is 2 mrem/wk.

Personnel access is controlled and no personnel are permitted within the inspection building during an inspection. Safety and operational interlock systems are provided to ensure that radiation production is terminated if any doors or other means of access are opened. Maximum radiation levels in areas expected to be occupied by personnel was measured as 0.450 mrem/hr. Considering the occupational plan of 4 hours of beam on time per week, the maximum radiation level in occupied areas is 1.8 mrem /wk, well below the regulatory requirement of 10 mrem/wk.

Radiofrequency levels associated with the high voltage power supply are well within the limits established in Part 18 of the FCC rules and several orders of magnitude below that considered to be hazardous as published in the American

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National Standards Institute Standard C95.1.

Small quantities of the nonflammable inert gas Sulfur Hexafluoride are used as the insulator for high voltage components. The components are sealed and the SF<sub>6</sub> is not normally emitted into the atmosphere. The use of the gas insulation material has been standard for most high voltage applications over the past twenty years. The only hazards listed by the American Conference of Government Industrial Hygienists (ACGIH) are those associated with handling of pressurized containers and the risk of suffocation if the gas were released in an unventilated space and displaces the oxygen. In the event of an accident, any gas released into the atmosphere will dissipate similar to Helium.

5. Identification of chemical substances that are subject to the proposed action:

The proposed action is applicable to linear accelerators as a source of x-radiation with energies of up to 10 MeV. The proposal also includes a dose limit of 0.5 Gy for the inspection.

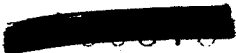
6. Introduction of substances into the environment

There are no substances introduced into the environment other than the x-radiation which is expected to be emitted during use of the radiation source for the cargo imaging.

The effect of radiation exposure to food stuffs has been studied over the past thirty years and is well known. In 1980, the Food and Drug Administration Irradiated Food Committee concluded that food irradiated at a dose not exceeding 1 kiloGray is safe for human consumption. More specifically, the use of linear accelerator produced radiation of up to 10 MeV for inspection purposes was the subject of a World Health Organization Consultation, convened in cooperation with the International Atomic Energy Agency (IAEA) in 1989. The Consultation was chaired by a representative from the United States and included Dr. George Pauli of the Food and Drug Administration as a participant. The Consultation results were published as "Food safety aspects relating to the application of x-ray surveillance equipment: Memorandum from a WHO meeting," Bulletin of the World Health Organization 68(3) 297-301 (1990). A copy is provided as Attachment 1. Papers prepared by participants from the USA, Hungary, and Mexico discussed the induced activity, microbiological, and toxicological effects (Attachments 2, 3, and 4). These reports, published literature, and prior FDA studies all indicate that 10 MeV x-radiation has no detectable effect on food irradiation at dose levels below 0.5 Gy.

000375

An inspection facility must be designed and constructed to provide both ionizing and nonionizing radiation shielding



sufficient to maintain accessible radiation levels well within the requirements of local, state, and federal requirements. Employees of the facility are subject to the occupational radiation control programs of State and local authorities as well as the Occupational Safety and Health Administration requirements. The pilot test facility located in Tacoma, Washington is fully compliant with applicable occupational exposure requirements. The linear accelerator radiation source complies with the requirements of the Federal Food, Drug, and Cosmetic Act, Subchapter C - Electronic Product Radiation Control. Linear accelerators are not subject to Nuclear Regulatory Commission regulation.

There is no radioactive or other toxic waste generated by inspection facilities.

Approval of the proposed action will have no impact upon compliance with current emission requirements. Failure to approve the action will mean that food contents of containers will have to be either removed prior to inspection, or the container must be manually searched and examined. Physical examination of cargo containers and vehicles adds a significant risk of injury to personnel.

Linear accelerators are used throughout industry at present for a variety applications, including radiography. The introduction of this application for cargo inspection will involve existing technologies for production of equipment and facilities. The additional number of sources produced as a result of this application is not significant and will not significantly affect the waste generation or emissions.

7. - 11. Not applicable

12. **List of preparers:**

This analysis has been prepared by Edwin A. Miller, RAC of C. L. McIntosh & Associates, Inc. A copy of Mr. Miller's resume is attached as Appendix A. A copy of C.L. McIntosh's flyer describing skills and services is attached as Appendix B.

13. **Certification:** The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of the firm or agency responsible for preparation of the environmental assessment.

(Date)

October 31, 1992

(Signature)

Edwin A. Miller

(Title)

Senior Consultant

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14. **References:** None provided

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15. Not applicable

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Attachment 1

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## Food safety aspects relating to the application of X-ray surveillance equipment: Memorandum from a WHO meeting\*

*Inspection of food-containing cargoes using X-rays is safe since no detectable radioactivity will be induced in the foodstuffs provided that an energy level of 10 MeV and a dose of 0.5 Gy are not exceeded.*

### Introduction

Many countries have regulations permitting the irradiation of foodstuffs. In most cases, these regulations conform to the Codex General Standard for Irradiated Foods (1), and in particular specify that X-rays used for this purpose should be generated from machine sources operating at or below an energy level of 5 mega-electron-volts (MeV). This limit has been chosen in order to stay well below the energy level where significant induction of radioactivity in the irradiated food may be expected.

Ionizing radiation is used not only to accomplish an effect on food, but also in connection with process and quality control (e.g., detection of the level of filling in cans and of foreign-bodies in containers) and in connection with the use of X-ray surveillance

equipment. WHO has recently been informed of new technological developments that have made it possible to use higher energy X-ray systems for the examination of large cargo containers and cargo vehicles to detect the presence of contraband such as illegal drugs, explosives and guns. Some Member States of WHO have already expressed interest in the use of such surveillance equipment. However, for penetrating large cargo containers, these systems operate with X-ray energies of over 5 MeV.

Although there may be considerable advantages in using this new technology in combating terrorism, etc., countries may be hesitant in allowing the use of such equipment on cargoes containing food because the energy level is in excess of that specified for food irradiation by the Codex Alimentarius Commission.

It was for this reason that WHO, in cooperation with IAEA, convened a meeting to seek international consensus on the food safety aspects arising from the use of high-energy X-ray surveillance systems. All companies known to WHO as developers or manufacturers of X-ray surveillance equipment were invited to participate. Their representatives presented technical information on such equipment and surveillance systems at the meeting.

The objectives of the meeting were:

- to investigate the usefulness of inspecting food-containing cargoes with the help of ionizing radiation;
- in the event of an affirmative answer, to define the parameters (energy-level and dose) necessary for large cargo surveillance with X-rays; and
- to consider possible health consequences from exposing food to X-rays with energies greater than 5 MeV and an absorbed dose in the range of 0.5 gray (Gy), in relation to induction of radioactivity; toxicological, nutritional and sensory considerations; and microbiological considerations.

000379

\* This Memorandum is based on the report of a WHO Consultation, convened in cooperation with the International Atomic Energy Agency (IAEA), which met in Neuenberg/Munich, Federal Republic of Germany on 13–17 November 1989. The participants were A.M.I. Alsayyid, Doha, Qatar; K.J. Dale, London, England; J.F. Olan, Karlsruhe, Federal Republic of Germany; J. Farkas, Budapest, Hungary (*Rapporteur*); M. Frisset, Bilthoven, Netherlands; H. Fröhlich, Frankfurt, Federal Republic of Germany; J.H. Hubbel, Gaithersburg, MD, USA (*Chairman*); J.R. Lujan, Mexico DF, Mexico; and G. Paull, Washington, DC, USA, *Secretariat*; K.W. Bögl, Berlin (West); A. Brynjolfsson, Wageningen, Netherlands; F.K. Käferstein, WHO (*Secretary*); A.-M. Schmitt-Hannig, IAEA; R.B. Singh, London, England; and H. Slitt, WHO, *Joint FAO/WHO Food Standards Programme*; E. Casadei, FAO, Rome, Italy. In addition, companies interested in X-ray surveillance equipment were represented by G. Gaus and C. Koch, Wiesbaden, Federal Republic of Germany; C.T. Blunden and G. Bennett, Bristol, England; and C.S. Nunan, Palo Alto, CA, USA. Requests for reprints should be sent to Dr F.K. Käferstein, Food Safety Unit, Division of Environmental Health, World Health Organization, 1211 Geneva 27, Switzerland. A French translation of this Memorandum will appear in a later issue of the *Bulletin*.

## Cargo Inspection

### *Is inspection with X-ray surveillance equipment useful?*

A major commitment of the customs authorities the world over is the fight against illegal trafficking in contraband such as drugs and arms. There are at least two factors which have an important bearing on the efficiency with which this task is performed: (1) the need to unpack and repack cargo items; and (2) the huge volume of cargoes at the present time and the increases anticipated in the future.

At Hamburg port, for instance, container traffic increased by 11.7% in 1988 to a total of 1.6 million containers. Dover and Southampton ports together handle approximately 20 tonnes of food per minute every day, which amounts to some 9.5 million tonnes/year. Throughput in the State of Qatar is some 20-40 trailers of foods each day. Similar considerations apply to air cargo. At Frankfurt International Airport, for example, 2.2 million individual consignments are handled annually by the customs authorities; an expansion by about 33% is expected by the year 2000. All the above figures are likely to increase with the anticipated rise in world food trade.

Control procedures for detecting and preventing contraband fall into a number of categories, such as the use of (1) conventional manual control; (2) dogs for detecting drugs and explosives; (3) chromatographic, spectroscopic and related methods; and (4) X-ray surveillance.

The advantage of the first three of these methods is the immediate provision of incriminating evidence, thus permitting direct assessments to be made. A disadvantage of the second and third methods is that these are highly specialized techniques and therefore of limited general applicability. Also, for biological reasons, dogs cannot repeatedly provide satisfactory results over extended periods. The most important drawback of all three methods is that they are time-consuming and labour intensive and, consequently, do not permit a high throughput of goods generally and large cargo containers in particular.

The fourth method, X-ray surveillance, is a rapid and efficient tool for the systematic and serial inspection of cargoes. However, X-ray surveillance systems currently in use operate at 140 kilovolts (i.e., energy levels<sup>a</sup> up to 0.14 MeV); because of this technical limitation, present systems allow for the inspection of small cargoes only. It is understood that recent

developments, using surveillance equipment with X-ray energy levels of up to 10 MeV, will enable large cargo containers to be screened without the need for opening the container and unpacking the goods.

This new technique will therefore facilitate the checking of large volumes of bulk consignments such as perishable goods (e.g., fresh food, flowers, etc.), textiles and leather goods without the need for unpacking. This is a particularly important consideration in view of the extraordinary inventiveness of smugglers in thinking up places and means of concealment. Perishable goods are an example in point; because of the known difficulties in handling such cargoes (time constraints, financial penalties), these goods are being used, increasingly, to conceal contraband, mostly drugs. It should be noted that the use of high-energy X-ray equipment requires experienced personnel trained in image interpretation and in its safe operation (for details, see Annex page 301).

Any development which facilitates rapid screening of large cargo containers will be advantageous to the customs and other control authorities. However, the technical feasibility and health consequences of such high-energy surveillance systems are issues that are discussed below.

### *Parameters necessary for X-ray surveillance of large cargo containers*

**Energy levels.** X-ray surveillance of large cargo items with thicknesses of the order of 2.5 m of water equivalent, or 30 cm of steel, is not possible without increasing the penetrating power of the X-ray beam. The penetrating power can be increased only by increasing the energy levels from those at present used for luggage inspection, typically up to 0.14 MeV, to energy levels of the order of 5 to 10 MeV.<sup>a</sup>

For successful imaging, including use of various kinds of image enhancement techniques, the maximum tolerable attenuation of the primary X-ray beam in traversing the cargo unit appears to be between  $10^{-4}$  and  $10^{-3}$ . The  $10^{-4}$  figure comes from presentations at this Consultation by representatives of companies producing fan-beam, moving-cargo high-energy X-ray surveillance equipment. The  $10^{-3}$  figure was inferred from published information on rocket-motor flaw detection in 50 cm of steel using 16 MeV X-rays (2).

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<sup>a</sup> For the purpose of this report, the term "energy level" is defined as the maximum photon energy producible by the X-ray source.

<sup>a</sup> One company described X-ray surveillance equipment using maximum energy levels of 8 MeV; another company demonstrated images derived from equipment operating at energy levels between 6 MeV and 10 MeV; and a third company suggested the possibility of using energy levels greater than 10 MeV.

The penetrating power of the X-ray beam does not increase indefinitely with increasing photon energy. There is a minimum in the attenuation cross-section vs. photon energy, above which the X-ray beam becomes less penetrating (3). For carbon, this minimal attenuation energy is 55 MeV, but drops to 8 MeV for copper and to 3.5 MeV for lead.

Another factor to be considered is the contribution to the attenuation from photonuclear interactions (4) in the 6–30 MeV region which accounts for only 2–6% of the total attenuation, but which can be a major mechanism for inducing radioactivity in the cargo material. This consideration is discussed in more detail below.

**Dose levels:** Information on the dose requirements for imaging with multi-MeV photons appears to be currently available only from commercial developers of such equipment.

For imaging with a cone-beam and a two-dimensional imaging screen (stationary cargo), the presentation by a representative of a developer of this type of equipment highlighted the need for a dose of 0.05 Gy at the surface of the cargo nearer to the X-ray source. This would imply a dose at the detector side of the cargo of  $0.05 \times 10^{-4}$  Gy (i.e.,  $5 \times 10^{-4}$  Gy) required by the detector system to produce an acceptable image.

For imaging with a fan-beam (moving cargo) facility using two beams at right angles, a much lower dose may be possible (in this context, a dose as low as 0.00025 Gy at the source side was quoted by one producer).

To allow for flexibility, for overlap of the exposures in some systems, for sufficient resolution, and for the need to re-examine cargoes in some instances, the Consultation considered a maximum dose of 0.5 Gy absorbed by the food.

## Possible health consequences

### *Exposure of food to X-rays with energy levels >5 MeV and a maximum dose of 0.5 Gy*

**Induction of radioactivity.** Several possibilities exist to induce radioactivity in food. The induction depends on an interaction between X-ray photons or neutrons with atoms in the food. Most interactions of this kind do not lead to the induction of radioactivity.

One type of interaction produces radioactive isomers. Energy from a photon is absorbed by an atom and afterwards emitted as radiation. Neutrons may be emitted following interactions of photons with atoms in the food (e.g., deuterium), or from outside sources (for example, as used in a thermal neutron detection scanning device). The absorption

of a neutron by an atom may also induce activity. Electrons induce radioactivity primarily by indirect means; photons are created (*Bremsstrahlung*) as the electrons strike the target material. These photons, in turn, interact with the nucleus of the atom in photonuclear reactions. Many of these reactions have threshold energies below which reactions do not occur. Thresholds are always dependent on the isotope and the type of reaction. All these physical processes are well known and documented and amenable to calculation. Results of such calculations are reported by Becker (5,6) and by Leboutet & Aucoutuviev (7).

Based on such calculations, the Consultation recognized that high-energy radiation can induce radioactivity in any absorbing medium, such as food. For example, one can calculate that even natural background radiations (e.g., cosmic rays) induce radioactivity in food. The factors affecting the radioactivity include the type of radiation (electromagnetic, probability of induced electron or neutron), the energy of the radiation, and the particular elements found in the food. These factors can also interact; for example, high-energy X-rays can induce reactions that produce neutrons, leading to further reactions caused by the neutrons.

Experimental studies that are relevant to determine the effects of low-dose/high-energy X-rays on food are usually not designed to determine induced radioactivity at the combinations of energy level, dose, and time after exposure that would be used in surveillance systems. However relevant experimental data are available from studies designed to evaluate the use of activation analysis and the application of X-rays and electrons in food irradiation and medical uses at energy levels up to 24 MeV and at doses up to 50 kGy. Such studies, both theoretical and experimental, can be used to extrapolate downwards to a lower dose such as that of 0.5 Gy considered by the Consultation for surveillance systems. These studies show no evidence that detectable levels\* of radioactivity would be induced at these lower doses.

In light of the large variations of background radioactivity in food that are of no concern, the Consultation concluded that radioactivity below the detection limit is also of no concern. A criterion of no detectable, induced radioactivity may be more strict

000381

\* All foods contain radioactivity, usually at levels in the range of 30–300 becquerel/kg. The amount of radioactivity in any specific food varies, depending on its elemental composition. The amount of increased radioactivity that can be measured is typically about 1% of the natural background in the food. For the purpose of this report, the Consultation considered this level to be the detection limit.

than necessary. However, present-day technology is capable of producing X-ray surveillance equipment which does not induce detectable amounts of radioactivity. Therefore, such a criterion provides a sufficient margin of safety to eliminate the need for considering cumulative effects of repeated X-ray surveillance inspections or occasional deviation from intended conditions of use due to human error.

*Toxicological, nutritional and sensory considerations.*

The Consultation considered the question of whether high-energy X-ray surveillance of food-containing cargo might cause chemical changes of toxicological or nutritional concern, or changes in the sensory quality of food. The conclusion was that, at the considered radiation dose of 0.5 Gy for X-ray cargo inspection, radiation-induced chemical changes in foods are so minute that no toxicological risks, losses of nutrients or changes in sensory quality can be foreseen. The dose level that might require consideration of such risks or changes is considerably greater than that needed for surveillance; therefore, even repeated inspections of the same cargo would not be of concern.

*Microbiological considerations.* The microbiological safety of irradiated foods has been investigated in many laboratories in relation to food preservation by ionizing radiation, and was a subject of discussion at several international meetings of experts, including the Joint FAO/IAEA/WHO Expert Committee on Wholesomeness of Irradiated Food (8). The conclusion of these reviews was that the microbiological safety of irradiated food is fully comparable with that of foods preserved by other acceptable preservation methods.

Regarding the energy levels of X-ray surveillance equipment which are higher than those at present permitted for food preservation, the Consultation concluded that the events following the primary interactions, including chemical and radiobiological effects, are the same and are independent of the different proportion of various primary energy absorption processes during interaction of X-rays with matter as a function of increasing photon energies. Thus, in principle, the same main questions which have been scrutinized in the past in relation to microbiological safety of radiation-preserved food may be considered also for high-energy X-ray surveillance of food. However, the much lower dose requirement of the latter technique should be taken into consideration. Regarding dose requirement for selective changes in the composition of the microflora and for changes in the diagnostic characteristics

of microorganisms, and considering the fact that nothing of significance has been found regarding radiation-induced mutants even at the dose levels of food preservation by irradiation, the Consultation concluded that no microbiological hazard will arise from the use of the proposed X-ray surveillance systems.

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## Conclusions

The Consultation concluded that of all the issues discussed, only the induction of radioactivity may be of concern regarding the potential effects of health. Evaluation of the likelihood of inducing radioactivity in food has mostly been based on theoretical calculations because the X-ray surveillance systems currently under consideration are not capable of producing detectable levels of activity.

Calculations applied to the different possibilities can be quite complex. It is not essential to make precise calculations, however, if a sufficient safety margin is built in to the deliberation. This condition is met when no detectable radioactivity is induced in foodstuffs.

The Consultation concluded, on the basis of available evidence, that no detectable radioactivity will be induced in foodstuffs when an energy level of 10 MeV and a dose of 0.5 Gy are not exceeded. The safety of the food will not be affected as a consequence of such exposure.

However, this conclusion is not intended to preclude other safe surveillance systems designed to operate at a higher energy level or dose. In such cases, assurance should be provided that, at the point of consumption, food would not contain a measurably detectable amount of induced radioactivity.

## Acknowledgements

The Consultation was supported by a grant from the United Kingdom government.

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## References

1. Joint FAO/WHO Food Standards Programme. Codex general standard for irradiated foods and recommended international code of practice for the operation of radiation facilities used for the treatment of foods. *Codex alimentarius*, Vol. XV, 1st edition. Rome, Codex Alimentarius Commission, 1984.

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2. Bakke, T.O. (quoting T.E. Kirchner, American Science and Engineering Inc., Cambridge, MA), Giant scanner inspects rocket motors. *Popular science*, 224: 95 (1984).
3. Hubbell, J.H. et al. Pair, triplet, and total atomic cross-sections (and mass attenuation coefficients) for 1 MeV-100 GeV photons in elements Z=1 to 100, *J. phys. chem. ref. data*, 9: 1023-1147 (1980).
4. Fuller, E.G. & Hayward, E., ed. Photonuclear reactions Stroudsburg, PA, Dowden, Hutchinson & Ross, 1976.
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6. Becker, R.L. A determination of the radioactivity induced in foods as a result of irradiation by electrons of energy between 10 and 18 MeV. Natick, MA, US Army Natick Research and Development Command, 1979.
7. Leboulet, H. & Aucouturier, J. Theoretical evaluation of induced radioactivity in food products by electron and X-ray beam sterilization. *Radiat. phys. chem.*, 25: 233 (1987).
8. WHO Technical Report Series No. 659, 1981 (*Wholesomeness of irradiated food: report of a Joint FAO/IAEA/WHO Expert Committee*).

## Annex

### Operational radiological safety aspects

Electron linear accelerators are being used throughout the world in increasing numbers in a variety of important applications. Foremost among these is their role in the treatment of cancer with both photon and electron radiations in the energy range 4-40 MeV. To a greater extent linear accelerators are replacing  $\text{Co}^{60}$  sources and betatrons in medical applications. Commercial uses include non-destructive testing by radiography, food preservation, product sterilization and radiation processing of materials such as plastics and adhesives. Scientific applications include investigations in radiation biology, radiation chemistry, nuclear and elementary-particle physics and radiation research.

Guidelines and standards on the radiological safety aspects of the operation of such accelerators

have been developed on a national<sup>a</sup> and international<sup>b</sup> basis.

In view of the rapidly growing number of cargo container shipments throughout the world, a new field of application for linear accelerators with photon energies of about 10 MeV has been established for X-ray surveillance of large containers.

In principle, the same registration, licensing and inspection procedures established by the appropriate regulatory authority apply as for all linear accelerators operating in the same energy range. In countries where a proper radiation protection infrastructure is not available, the Consultation suggests that the manufacturer should notify the IAEA. However, the responsibility for protection of personnel, facilities, the public and the environment from all types of hazards related to linac (linear accelerator) operations must rest with the management of the organization using these systems. Under its direction, a safety unit should be established and a safety programme appropriate to the special needs of the application should be developed and implemented.

A radiation safety programme should be developed in coordination with the facility's overall safety programme, and in compliance with national, regional and local requirements. Recommendations of international organizations such as IAEA, the International Commission on Radiological Protection (ICRP), the International Commission on Radiation Units and Measurements (ICRU), the International Electrotechnical Commission (IEC) and the Commission of the European Communities, as well as national commissions, should be considered in the development of this programme.

<sup>a</sup> United States Atomic Energy Commission. *Safety guidelines for high-energy accelerator facilities*. Washington DC, National Accelerator Committee, USAEC Division of Operational Safety, 1967 (see the latest version).

<sup>b</sup> United States Atomic Energy Research and Development Administration. *Operational safety standards*. Washington DC, AECM Section 9550, USERDA (periodically revised).

<sup>c</sup> IAEA Technical Report Series No. 188 (*Radiological safety aspects of the operation of electron linear accelerators*). Vienna, International Atomic Energy Agency, 1979.

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Attachment 2

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AGENDA ITEM 6.1: POSSIBLE HEALTH CONSEQUENCES FROM EXPOSING FOOD TO A MAXIMUM ENERGY LEVEL OF  $> 5$  MeV AND A MAXIMUM DOSE IN THE RANGE OF 0.5 Gy: INDUCTION OF RADIOACTIVITY\*

Donald L. Thompson\*\*

and

George H. Pauli\*\*\*

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Abstract

This working paper discusses experimental and theoretical work concerning the possible induction of radionuclides in food by high energy x-ray systems used for cargo surveillance. Activities found under a variety of conditions are compared to activities from other sources.

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\*Draft working paper for WHO consultation on Food Safety Aspects Relating to the Application of X-ray Surveillance Equipment convened in cooperation with IAEA, Neuherberg/Munich, Federal Republic of Germany, 13-17 November, 1989

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000385



It has been proposed to conduct x-ray surveillance of cargo food containers with equipment operating at voltages up to 10 MeV and with doses up to 0.5 Gy. During exposure to high energy photon beams, radioactivity can be induced in foods. Information on such processes is available, generally from research on sterilization of food at much larger doses, and often at higher energies than 10 MeV.

Within the proposed range, two processes appear to be of concern: isomer activation by photon absorption and delayed photon emission, and creation of radioactive isotopes by photon absorption followed by neutron emission. Some neutrons may subsequently be absorbed to create other radioactive species.

Isomer activation can occur with energies as low as 0.1 to 3 MeV and several photoneutron thresholds for specific isotopes can be demonstrated below 10 MeV. When photoneutron or other particle emission thresholds are exceeded the probability of such reactions is higher than for isomer activation or neutron interaction.

Whether induced activity becomes a hazard to health depends on beam energy, half-life of the activation product, total dose, and concentration of the target element in the food. Fortunately, most induced radionuclides have very short half-lives, most target elements in food exist in trace amounts, and the higher atomic-numbered elements, which have higher activation yields, are the least abundant trace elements.

Among the elements from hydrogen to bismuth, only 15 have isomers of stable isotopes with half-lives between 0.5 minutes and 12 years. Of the 22 isomers in this group, only 4 are from elements found in food that have half-lives substantially greater than one hour, i.e., cadmium-111m, cadmium-113m, tin-117m and tin-119m (m refers to a metastable isomeric form of an isotope).

Glass and Smith (1) conducted a series of measurements on the induction of these 22 radioactive isomers, as well as isomers of iron and zinc, by photon beams. The sources employed were cesium-137, cobalt-60, spent reactor fuel elements, and 4-, 8-, 16-, and 24 MeV x-rays. In addition to irradiation of sample elements, they exposed samples of food including beef, bacon, shrimp, chicken, and green beans.

Exposure of pure samples of iron and zinc gave activities of less than 1 Bq per gram of the element at photon energies up to 8 MeV. Above that energy, photoneutron products masked isomeric activities. A sample of silver was measured at less than 260 Bq per gram with cobalt-60 energy and 4 MeV x-ray, but became masked at 8 MeV. Lead reached 52 Bq per gram at 4 MeV, then leveled at 7.4 MBq per gram for 16- and 24 MeV. Cadmium isomers increased in concentration with photon energy reaching 74 kBq

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per gram at 8 MeV, after which it was masked. Tin measured 111 mBq per gram at 4 MeV and leveled to 11 Bq per gram for 16- and 24 MeV. Values are for 50 kGy doses.

Irradiated food and food ash samples were measured by both gamma and beta counting equipment. Doses varied: cesium-137, cobalt-60 and fuel elements were 100, 80, and 140 kGy, respectively. The 4 MeV and 8 MeV exposures were 100 Gy and 500 Gy, while 16 MeV and 24 MeV were 2 kGy and 3 kGy.

Bacon, shrimp, and chicken yielded net positive gamma counts when exposed to fuel elements. Bacon was also positive for the 8 MeV exposure but not the 16 MeV. Ash samples of the 8 MeV bacon and the fuel element chicken samples did not confirm the net counts, leaving the fuel element bacon and shrimp as "anomalous" results. It should be noted that the cobalt-60 and fuel element samples were measured 60 days post-irradiation, and others were at 100 days post-irradiation. Only cadmium-113m and tin-119m, of the 4 expected products, have sufficient half-lives to be detected after this interval.

The authors concluded that no definite isomer radioactivity had been induced. They supported this with calculations of activity concentrations for 50 kGy exposures showing that 4 MeV and 24 MeV yields would be so low as to be experimentally undetectable in foods. Calculated values for the most important isomers, those of tin, were at least a factor of 1,000 below the naturally occurring levels of potassium-40, carbon-14, tritium, and radium-226.

Although the experiments were designed to evaluate isomer production, the equipment also detected photoneutron products created by the higher energy beams. At 16 and 24 MeV, there was spectral indication of sodium-22 activity. Previous experiments had shown rubidium-84 could also be produced at these energies.

Glass and Smith provided a table of calculated values for photoneutron products at 24 MeV. The radionuclides sodium-22, phosphorus-32 and -33, rubidium-84, iron-53, zinc-65, and iodine-126 at 50 kGy doses fell in the same range of activity concentrations as naturally occurring nuclides in food. (The 50 kGy dose, though not stated in the table, is clearly intended, as shown by comparison to activities given on an accompanying table in their report.)

One photoneutron reaction not reviewed in the above report is the production of sodium-24. Because of the delayed counting interval used, this 15-hour half-life nuclide would have decayed to undetectable levels.

Koch and Eisenhower (2) in their review of food irradiation illustrated results of calculated and experimental yields from

DUPLICATE

50 kGy electron beams. They determined sodium-22 activities in ham and beef, and sodium-24 activities in ham, beef, and pork. For both radionuclides, ham yielded the highest activities. Sodium-22 (threshold 12.4 MeV) increased activity with increasing beam energy approaching 1.5 mBq per gram at 15 MeV and 150 mBq per gram at 24 MeV. Sodium-24 is produced by absorption of a thermal neutron and theoretically can appear as a by-product of photoneutron reactions below 10 MeV. However, at 10 MeV, the activity due to a 50 kGy dose is about 2 mBq per gram, and at 24 MeV is nearly 3.7 Bq per gram. The efficiency of a photoneutron reaction from photon beams is about 10 times greater than an electron beam at 30 MeV and somewhat more than that at lower energies.

Koch and Eisenhower also referenced experimental data on isomer activities in beef for various photon energies and 50 kGy doses. The highest level listed was 37 mBq per gram at 24 MeV for strontium-87m (half-life 2.8 hr.). This activity was 2000 times less at 8 MeV, however. The longest lived isomers were tellurium-123m (104 days) and barium-135m (28.7 hrs). The tellurium isomer yielded  $3 \times 10^{-7}$  mBq per gram at 16 MeV, and barium measured less than 1 mBq per gram at 24 MeV.

For any photon beam, it can be assumed that the induced activity is proportional to the total dose. The above referenced activity levels in food can be used to predict levels generated by surveillance exposures at the lower dose. Thus, activities produced by a dose of 50 kGy decrease by a factor of 100,000 for photon beams at a dose of 0.5Gy. Likewise, data on pure elements can be used with the elemental composition to assess maximum possible activities.

Although the experimental data and calculated estimates cited do not address specifically all possible combinations of food, energy level, and time to measurement after irradiation, in no case do the authors indicate a significantly increased level of radioactivity for foods irradiated at a dose below 10 MeV, even at extremely high doses. While one cannot rule out the possibility of detectable levels of induced radioactivity from high doses of 10 MeV photons, the extremely low dose needed for surveillance counterbalances any increased probability due to the higher energy. Although health protection guidelines should be based on the biologically equivalent dose delivered by the particular radionuclide, a sufficiently low activity level of any kind can make such a refinement unnecessary.

Comparison may also be made to several published recommendations for health protection, although one should remember that suitable standards for unavoidable contamination are not necessarily appropriate for more readily controllable situations. The Maximum Permissible Concentrations in water (MPC) for U.S. occupational exposure on a weekly basis (3) are almost all set

DUPLICATE

at 3.7 Bq per cubic centimeter or higher. Of the exceptions, only iodine-126, with an MPC of 2 Bq per cubic centimeter, would appear to be of concern in food. Average body burdens for non-occupationally-exposed persons are set at 1/10th of that for radiation workers.

Koch and Eisenhower illustrate the use of MPC values by considering ham which, when exposed to 50 kGy of 24 MeV electrons, has induced 52 mBq per gram of sodium-22. The MPC for this nuclide in water is about 1500 mBq per cubic centimeter for non-radiation workers. Consequently, in the extreme case that ham constituted the total daily diet, the dose due to ingestion would be 28 times less than permitted in an equivalent mass of water. Assuming a photon beam generates 10 times the activity, the activity concentration would still be below the MPC for this unusual diet.

Report No. 30 of the International Commission on Radiation Protection gives values for the annual limit of intake (ALI) through occupational exposure to many radionuclides. Some ALI's for nuclides most likely from food irradiation are tin-119m at 200 MBq, sodium-22 at 20 MBq and sodium-24 at 100 MBq. As an example, allowing a factor of 10 on the ALI for non-radiation workers, and applying it to a hypothetical daily diet of 2200 grams containing sodium-24, would be equivalent to each meal containing 12 Bq per gram if consumed 24 hours after irradiation.

In response to the Chernobyl incident, the U.S Food and Drug Administration established Levels of Concern for acceptable concentrations of radionuclides in imported food (4,5). For iodine-131 in infant food, the monitoring level was 36 mBq per gram. For combined activities of cesium-134 and -137 in either infant or adult food, the monitoring level was 370 mBq per gram. The monitoring level was based on an operational assumption that iodine-131 would be present in imported food for about 60 days, and cesium isotopes for about one year.

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Attachment 3

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Microbiological considerations on possible health consequences  
from exposing food to X-rays of energy levels higher than  
5 MeV and a maximal dose of 0,5 Gy

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Introduction

Concerning the suggested use of surveillance of large cargo containers with high energy X-ray systems, the WHO intends to evaluate food safety aspects of this technology. In relation to this interest, the writer has been requested to consider microbiological implications from exposing food with an ionizing energy level higher than 5 MeV, and a maximal dose of 0,5 Gy. The following considerations are based on these given parameters without investigating the technical feasibility of X-ray surveillance of large cargo containers, or the actual energy-and dose requirements of its specific applications.

Microbiological safety of irradiated foods has been investigated in relation to food preservation by ionizing radiation by many laboratories and it was subject of discussions of international meetings of experts. A consultants'

000392



meeting jointly convened by FAO and IAEA has scrutinized microbiological aspects of food irradiation already in 1974 /FAO/IAEA, 1974/. Related detailed reviews have been published additionally /Ingram, 1975; Ingram & Farkas, 1977/. The conclusions of these reviews was that microbiological safety of irradiated food is fully comparable with that of foods preserved by other acceptable preservation methods. This conclusion was endorsed by the Joint FAO/IAEA/WHO Expert Committee on Wholesomeness of Irradiated Food /JECFI/ both in 1976 and 1980 /JECFI, 1977, 1981/. The subject was again considered at a meeting of the Board of the International Committee on Food Microbiology and Hygiene /ICFMH/ of the International Union of Microbiological Societies held in 1982 /ICFMH, 1983/, and at a Task Force Meeting on Public Information on Food Irradiation held by the International Consultative Group on Food Irradiation /ICGFI/ in 1988. The background paper of the latter meeting on microbiological safety of irradiated foods has been published recently /Farkas, 1989/. All these meetings of experts concluded that food irradiation introduces no special microbiological problem.. Governments in numerous countries established also their own independent expert committees to evaluate experimental evidence on irradiated foods. So far reports of such committees have been published, the conclusions of the Joint FAO/IAEA/WHO Expert Committee were reaffirmed.

000393



Food preservation by irradiation requires doses much higher than 0,5 Gy, and regulations on food irradiation including the Codex General Standard for Irradiated Foods list X-ray sources operating at or below an energy level of 5 MeV among acceptable radiation sources suitable for food irradiation. This energy limit has been chosen in order to stay well below the energy level where significant induction of radioactivity in the irradiated materials may be expected. Therefore, the present paper attempts to review

DUPLICATE

relevant information regarding the validity of the above conclusions on microbiological safety of irradiated foods if they were exposed to X-rays of energy levels higher than 5 MeV, and with an maximal absorbed dose of 0.5 Gy.

#### Interactions of high energy X-ray with matter

According to the knowledge on interaction of ionizing radiations with matter, the energy of X-and gamma rays is almost entirely absorbed by ejecting electrons from the atoms of the material through which they pass, and this process is almost independent of the manner in which these atoms are combined into molecules /Bacq & Alexander, 1966/. The secondary electrons produced are in fact the ionizing particles: almost all the ionizations are produced by the ejected electrons. In photon interactions with matter three processes are of importance: photo-electric absorption,

000394

Compton scattering and pair-production, depending on the photon energies involved. Photons having energies below 0,5 MeV may completely be absorbed and transfer their energy to an electron of one of the innermost orbitals which is ejected /photo-electric absorption/. Photons having higher energies than 0,5 MeV may collide with the loosely bound orbital electrons and are deflected with energies reduced by the amount imparted to the electrons /Compton effect/. These electrons are ejected and called Compton electrons. Photons having higher energies than 1,02 MeV may react with the electric field around the nucleus and convert all their energy to the production of an electron and a positron. This "pair production" uses up 1,02 MeV. The excess energy is imparted to the pair as kinetic energy. The two particles then lose their energy by collisions with electrons, but in addition the positron has the possibility, the greater the lower the kinetic energies, of "annihilation" with an electron. In this event, which all positrons eventually undergo, the mass of the two particles is lost and appears as energy of two quanta of gamma-rays. Consequently, although the proportion of primary energy absorption processes involved maybe different with > 5 MeV photons than with those permitted for food preservation by irradiation, the events following the primary interactions, including chemical and radiobiological effects are the same. Thus, microbiological considerations concerning

000395



effects of hard X-ray photons of  $\leq 5$  MeV, and hard X-ray photons of  $> 5$  MeV are also the same.

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Microbiological implications of irradiation of food  
during X-ray surveillance of cargo containers

In principle, the main questions concerning microbiological safety of radiation-preserved food may be considered also for food underwent X-ray surveillance, however, the much lower dose requirement of the latter shall be taken into consideration. The main questions concerning microbiological safety of irradiated foods are:

1/ Could selective changes in the microflora make known pathogens more likely to occur, or bring into prominence unfamiliar pathogens?

2/ Is it probable that "mutational" /including adaptive/ changes might make pathogens more virulent or more difficult to recognize, and could new pathogens arise in this way?

Changes in the microbial flora of foods

Considering the radiation resistance of food-borne microorganisms, no significant lethal effect /reduction of the viable cell count/ can be expected at 0,5 Gy /50 rad/ dose level, even under the most adverse environmental conditions influencing radiosensitivity of microbial cells. The lowest

000396



$D_{10}$  or  $LD_{90}$  values for the most sensitive species of vegetative bacteria are still in the order of 50 Gy /5 krad/, and even strains which were repair deficient shows  $D_{10}$  values higher than 20 Gy /Davies, 1976/. In a protective environment and complex substrates such as foods, the radiation resistance may be by an order of magnitude higher /ICMSF, 1980/.

DUPLICATE

Therefore, no change of the microbial community structure of food or of microbial competition can be expected as an effect of X-ray surveillance. Thus, X-ray surveillance of cargo containers would not present a hazard resulting from a shift in the microflora of food they contain. Radiation doses involved are also too low to result changes of the physical properties or chemical composition of food which would influence subsequent growth of food-borne pathogenic or spoilage microorganisms.

#### Induction/selection of "mutants"

It is well known that ionising radiations are mutagenic agents. However, exposure to sunlight, ultraviolet irradiation and even many traditional treatments among food technological processes can induce mutagenic changes, too /Ingram & Farkas, 1977/.

It is well established that the genetic material deoxyribonucleic acid /DNA/ is the best candidate for the primary chemical lesion in cellular radiobiology. To produce a mutant no more than a minor alteration must occur or remain unrepaired in the "target" DNA so that its biological replication is not prevented, but only slightly interfered with, thereby giving increases in the number of imperfect replicas /i.e. mistakes/ that are made. It is this altered DNA made during the course of biological synthesis that represents the mutant.

The number of mutations produced in a population is proportional with the dose of mutagenic agents /Ehrenberg, 1980, Leenhouts et al., 1981/

000397

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that the probability of mutation generally increases with dose, while that of survival declines. Thus yield curves always possess a maximum whose position and magnitude depends on the kinetics of the mutation and killing process /Eckhardt, 1980/. Assuming that mutation and killing are stochastically independent processes, in case of linear killing /exponential survival curve/ coupled with linear mutation induction, the position of the maximum yield occurs at a dose corresponding to one lethal hit, that is the 37 % survival level. For linear killing and purely quadratic mutation induction the maximum yield occurs at a dose corresponding to 14 % survival, etc. Thus, the very low dose required to X-ray surveillance would produce relatively less mutants than most application of food preservation by irradiation requiring much higher doses. Even in the latter field, the JECFI-s' search for radiation induced mutants revealed however nothing of significance /JECFI, 1977, 1981/.

The general mutational effect of irradiation will be damage, i.e. impairment of normal functions and introduction of new biological demands /Previtte et al.1970, Mossel, 1977, Maxcy, 1977; Maxcy & Rowley, 1978/. While this is likely to make organisms more difficult to grow and recognised, it is not likely to make them more pathogenic. In fact, no evidence has been reported of an irradiation-induced enhanced pathogenicity of food-borne microorganisms and no reports have been found suggesting the acquisition of pathogenicity of a non-pathogen. Neither irradiation of foods nor the widespread use of ionising radiation in the medical field have led to the appearance of alien pathogens, or enhanced infectivity of known pathogens.

Although in some experiments with specific inoculum ranges the reduction of high inoculum level of some toxigenic moulds by radiation doses, which were at least 1000-times

000398

higher than that required for the X-ray surveillance, resulted an increase in toxin production /e.g. Applegate and Chipley, 1973, Schindler et al., 1980/ others demonstrated that the same effect can be obtained simply by dilution of the inoculum /Sharma et al., 1980, Odamtten et al., 1980, Badawey, 1986/. Therefore, the increased toxin level is not related to specific radiation effects or introduction of more toxigenic mutants.

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#### Diagnostic characters

The reported evidence indicates that irradiation treatment induces only transitional changes in the surviving cells even at the relatively high dose levels required for preservation of food. Occasional changes in shape were temporary, except in extensively radiation re-cycled cells. The changes in biochemical pattern, or in growth response on selective media, were small and could usually be restored by resuscitation /Parisi & Antoine, 1975 /Ingram, 1975/. Changes that occurred were not sufficient to obscure general identity, though they occasionally made previous identification more difficult /ICMSF, 1980/. The very low dose of X-ray surveillance can be expected to cause much less radiation damaged cells.

#### General conclusion

On the basis of the aforementioned considerations and evidences, it can be concluded that, from the microbiological point of view, food which would undergo X-ray surveillance in cargo containers would not be different before and after the X-ray surveillance. The fact that the widespread medical use of radiation and the increasing use of food irradiation have caused no problems towards altered or more virulent forms of microorganisms, is a good indication that analogous difficulties are not likely with X-ray inspected foods.

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Attachment 4

POSSIBLE HEALTH CONSEQUENCES FROM EXPOSING FOOD WITH X-RAY SURVEILLANCE EQUIPMENT\*  
- TOXICOLOGICAL CONSIDERATION

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INTRODUCTION

WHO has been informed of new technological developments to use high energy X-ray systems for the examination of large cargo containers to detect the presence of contraband such as explosives and guns<sup>(1)</sup>. The cargo is exposed to X-rays with energy higher than 5 MeV and is assumed that a dose of 0.5 Gy is absorbed by stuffs for surveillance purposes. The use of X-ray systems with such energy levels for cargoes containing foodstuffs excess the level specified by the Codex Alimentarius Commission for food processing purposes<sup>(2)</sup>.

It is convenient to analyze the possible health consequences from exposing food to doses in the range of 0.5 Gy with X-rays with energy higher than 5 MeV, taking in account toxicological, nutritional and microbiological aspects, as well as the induction of radioactivity. The purposes of this working paper is to consider the information concerning the toxicological aspects.

TOXICOLOGICAL CONSIDERATIONS

From the toxicological consideration, foodstuffs exposed to X-rays are considered wholesome if the ionizing radiation has produce no toxic compounds in food.

After searching the literature, trough INIS from 1950-1989, there are no specific published or available papers or reports of toxicological work on food exposed to doses of 0.5 Gy with X-rays with energy higher than 5 MeV, so it is not possible the analysis directly.

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\* Working paper WHO/IAEA Consultation on Food Safety Aspects Relating to the Application of X-ray Surveillance Equipment, Neuherberg, FRG, November, 1989.

However, the analysis could be possible based in the findings related with food irradiation research, extrapolating to the very low dose that foodstuffs could absorb during X-ray surveillance and assuming that the used energy level causes no induced radioactivity problems and thus can not expose the consumer to radiation.

Since 1981, a Joint Expert Committee on the Wholesomeness of Irradiated Food, representing WHO, FAO and IAEA concluded that no hazard is involved in processing any food with ionizing radiation up to 10 kGy.

As result of the findings in animal feeding tests and knowledge about the nature and predictability of radiolytic products, procedures to investigate the toxicological safety of food exposed to ionizing radiation gradually focusing on the radiolytic products. The USA Food and Drug Administration Stating<sup>(3)</sup> that scientists should focus on the safety of the radiolytic products to evaluate the safety of irradiated foods, pointing out that the traditional animal feeding studies are inappropriate. However, is not necessary to extrapolate and examine for each food exposed to X-rays, for surveillance purposes. This standpoint is similar for the use of low energy X-ray inspection of food<sup>(3)</sup>.

The current understanding of the chemical effects of ionizing radiation on the composition of foods, permits to consider that although detectable, the chemical changes are too small<sup>(4)</sup>.

For each kGy of ionizing radiation absorbed by one kg of food approximately six chemical bonds are broken in each ten million chemical bonds present. The products that have been found by analysis are the same types of compounds already present in foods and produced by other accepted means of processing. No unique compounds have been found in food exposed to ionizing radiation in 35 years of research<sup>(5)</sup>.

The results indicate that the amounts of radiolytic products increase linearly with dose. Extrapolating to the dose of 0.5 Gy and assuming that each broken chemical bonds yields a radiolytic molecule, it means that the amount of radiolytic products decreases considerably.

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The dose of 0.5 Gy yielded concentrations of radiolytic products too low that they would be impossible to detect. If foods treated with higher doses are safe for human consumption, foodstuffs exposed to 0.5 Gy would be also safe, assuming that the energy level of X-ray for surveillance cause no radioactivity problems and thus can not expose the consumer to radiation.

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Appendix A

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PROFESSIONAL EXPERIENCE:

Consultant, C. L. McIntosh and Associates 1992-present

Provide consulting services to manufacturers or radiation emitting electronic products and medical devices on the requirements of the Food and Drug Administration. Areas of particular expertise include conformance to electronic product radiation safety performance standards, product certification processes, recall assistance, response to FDA inspections, complaint handling systems, and other recordkeeping and reporting requirements.

Director 1983-1992  
Division of Standards Enforcement  
Center for Devices and Radiological Health, FDA

Directed comprehensive enforcement program of the Radiation Control for Health and Safety Act for all types of radiation emitting electronic products consisting of analysis of manufacturers required reports, laboratory testing, field testing and factory inspection. Directed the efforts of approximately 45 staff persons as well as laboratory and field staff. Responsible for the development and implementation of policy and enforcement strategies.

Developed the program for assessment of medical devices to voluntary standards and a laboratory testing program for conformance to 510(k) specifications.

As a member of the Office of Compliance senior management team participated in development and implementation of enforcement policies for medical devices subject to the Federal Food Drug and Cosmetic Act. Member of the task force which developed the amendments to the GMP regulations. Served two details as the Acting Deputy Director, Office of Compliance and Surveillance assisting the Office Director in managing and directing the Center's enforcement program for medical devices and radiation emitting electronic products.

Actively participated in the development of international standards for diagnostic imaging and radiation therapy equipment. Served as a U. S. delegate to several committees and workgroups of the International Electrotechnical Commission and served as a member of the U. S. Technical Advisory Committees in those areas.

000408



Deputy Director  
Division of Compliance  
Bureau of Radiological Health, FDA

1982-1983

Assisted the Division Directory in planning, managing, and directing the Bureau's programs for enforcement of the Radiation Control for Health and Safety Act for all electronic products and the Federal Food Drug and Cosmetic Act for radiation emitting medical devices.

#### OTHER ACCOMPLISHMENTS

Developed the radiation safety performance standard for cabinet x-ray systems, including baggage inspection systems and served on the Presidential Commission for Airport Security.

Member, National Council on Radiation Protection and Measurements, Scientific Committee 28.

Member, American National Standards Institute (ANSI) Standards committee for non-medical radiation applications.

#### EDUCATION:

Western Illinois University  
B. S. in Physics, June, 1964

University of Minnesota  
MS in Radiological Health, June, 1967

#### AWARDS AND HONORS:

Outstanding Service Medal, Commendation Medal and others from the U. S. Public Health Service

Accelerated promotion for exceptional capability from the U.S. Public Health Service

#### PROFESSIONAL CERTIFICATION:


Regulatory Affairs Certified (RAC) by Regulatory Affairs Professional Society

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Appendix B

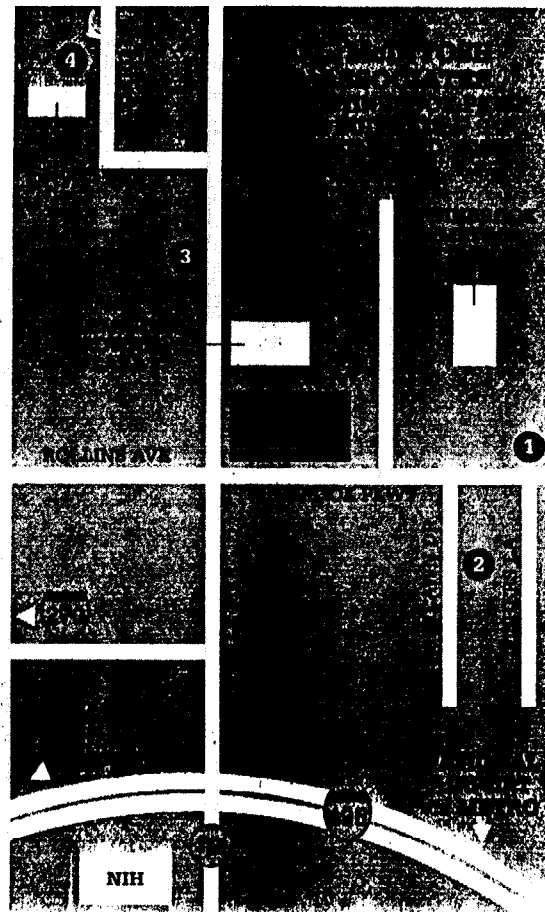
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- ② FDA Headquarters and Center for Drug Evaluation and Research
- ③ Center for Biologics Evaluation and Research
- ④ CDRH's Office of Compliance and Office of Device Evaluation

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**■ Gail Greenberg, Founder**

*Former manager of NIH's Heart, Lung and Blood  
Institute's cardiac studies data base*

**■ Walter E. Gundaker**

*Former Acting Director of CDRH and Director of  
CDRH's Office of Compliance, FDA*

**■ Robert L. Sheridan**

*Former Director of CDRH's Office of Device  
Evaluation, FDA*

**■ Edwin A. Miller**

*Former Director of the Division of Standards and  
Enforcement in CDRH's Office of Compliance, FDA*

**■ Thomas M. Tsakeris**

*Former Director of the Division of Clinical Laboratory  
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